



Attorney Docket No.: P-5235-US14

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): DALTON, James T. et al. Examiner: KUMAR, Shailendra

Serial No.: 10/849,039 Group Art Unit: 1621

Filed: May 20, 2004

Title: METABOLITES OF SELECTIVE ANDROGEN RECEPTOR MODULATORS
AND METHODS OF USE THEREOF

Mail Stop Amendment
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§1.56, 1.97 and 1.98, this Information Disclosure Statement includes Form PTO/SB/08:

1. ☒ listing documents including patents, publications and other information for consideration by the Examiner, however, since the subject application was filed after June 30, 2003, copies of United States patents and/or United States patent application publications are not included in this information disclosure statement; and/or
2. ☐ listing documents including patents, publications and other information that have been previously cited or submitted to the Patent Office in prior application U.S. Serial No. _____, filed _____ which is properly identified and relied on for an earlier effective filing date under 35 U.S.C. 120 for consideration by the Examiner; however, in accordance with 37 C.F.R. 1.98(d), copies of such documents are not included in this information disclosure statement; and/or
3. ☒ listing documents including patents, publications, and other information for consideration by the Examiner, copies of which are included with this information disclosure statement;
4. ☐ listing other information for the Examiner's consideration which was cited in a communication from a foreign patent office in a counterpart foreign application, a copy of which is included with this information disclosure statement.

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The information herein cited is only in fulfillment of Applicant(s) duty of candor in disclosing all information brought to Applicant(s) attention. This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that each or all of the listed documents are material or constitute "prior art". If it should be determined that any of the listed documents do not constitute "prior art" under United States law, Applicant(s) reserve the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Applicant(s) further reserve(s) the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the documents be applied against the claims of the present application.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each and every document cited (including any cited in applicant's specification which is not repeated on the attached Form PTO-1449) be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing on Form PTO-1449. Such initialing is requested even if the Examiner does not consider it to be prior art for any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application and is evidence that the Examiner has considered the document.

This Information Disclosure Statement is being filed:

- I) ☐ Within three (3) months of filing the subject Application or entry of the subject Application into the national stage or before mailing of the first Office Action on the merits of the subject Application or a request for continued examination thereof, whichever event occurs last pursuant to of 37 C.F.R §1.97 (b); or
- II) ☒ After the period specified in (I) but before the mailing date of either a final Official Action under 37 C.F.R §1.113 or a notice of allowance under 37 C.F.R §1.311 whichever occurs first and;

1. ☐ the undersigned hereby states that each item of information listed on the Form PTO-1449 was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement or (ii) not cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned after making reasonable inquiry, not known to any individual designated in §1.56(c) more than three (3) months prior to the filing of this information disclosure statement; or

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2. ☒ the undersigned hereby authorizes the Patent Office to charge the fee in the amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

III) ☐ After the period in (I) and (II) but before the payment of the issue fee and,

1. The undersigned hereby states:

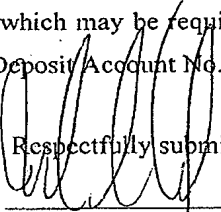
a) ☐ that each item of information cited on the form PTO-1449 was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three (3) months prior to the filing of this Information Disclosure Statement; or

b) ☐ that no items of information contained in Form PTO-1449 was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement; and

2. ☐ The undersigned hereby authorizes the Patent Office to charge the Petition fee in the Amount of \$180.00 under 37 C.F.R. §1.17 (p) to Deposit Account 50-3355.

Except for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §§1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account No. 50-3355.

Respectfully submitted,


Mark S. Cohen
Attorney/Agent for Applicant(s)
Registration No. 42,425

Dated: July 11, 2007

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PTO/SB/08a (07-05)
Approved for use through 07/31/2008. OMB 0651-0031
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	10/849,039		
		Filing Date	May 20, 2004		
		First Named Inventor	DALTON, James T.		
		Art Unit	1621		
Examiner Name	KUMAR, Shailendra				
Sheet	1	of	4	Attorney Docket Number	P-5235-US14

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	A	09/935,044	08/23/2001	Dalton et al.	
	B	09/935,045	08/23/2001	Dalton et al.	
	C	09/644,970	08/2/2000	Dalton et al.	
	D	6,019,957	02/01/ 2000	Miller, et al.	
	E	6,071,957	06/06/2000	Miller, et al.	
	F	6, 160,011	12/12/2000	Miller, et al.	
	G	4,636,505	01/13/ 1987	Tucker	
	H	4,880,839	11/14/ 1989	Tucker	
	I	4, 465,507	08/14/1984	Konno, et al.	
	J	3,875,229	04/01/1975	Gold	
	K	4, 139,638	02/13/1979	Neri, et al.	
	L	4,191,775	03/04/1980	Glen	
	M	4, 239,776	12/16/1980	Glen, et al.	
	N	4,386,080	05/31/1983	Crossley, et al.	
	O	4, 282,218	08/04/1981	Glen, et al.	
	P	5,609,849	03/11/1997	Kung	
	Q	5, 162,504	11/10/1992	Horoszewicz	
	R	5,656,651	08/12/1997	Sovak, et al.	
	S	6,838,484	01-2005	Steiner, et al	
	T	6,569,896	05-2003	Dalton, et al	
	U	6,998,500	02-2006	Dalton, et al	
	V	7,026,500	04-2006	Dalton, et al	

Examiner Signature		Date Considered	
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The collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Application Number	10/849,039
		Filing Date	May 20, 2004
		First Named Inventor	DALTON, James T.
		Art Unit	1621
		Examiner Name	KUMAR, Shailendra
Sheet	2	of	4
		Attorney Docket Number	P-5235-US14

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	W	WO98/53826		12/03/1998	Dalton et al.		<input type="checkbox"/>
	X	EP0 100 172		02/08/1984	Tucker		<input type="checkbox"/>
	Y	EP0 040 932		02/12/1981	Crossley et al.		<input type="checkbox"/>
	Z	WO95/19770		07/27/1995	Gray		<input type="checkbox"/>
	AA	EP 0253503		12/11/1991	Tucker		<input type="checkbox"/>

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴ Kind Code ⁵ (if known)				
	BB	WO 02 00617		01-03-2002	Bristol Myers Squibb		<input type="checkbox"/>
	CC	WO 01 27622		04-19-2001	Bristol Myers Squibb		<input type="checkbox"/>
	DD	WO 01 28990		04-26-2001	Nobex Corporation		<input type="checkbox"/>
	EE	WO 01 34563		05-17-2001	Nobex Corporation		<input type="checkbox"/>
	FF	WO 98 05962		02-12-198	Panvera Corporation		<input type="checkbox"/>
	GG	EP 000 2892		02-06-1985	Imperial Chemical Indust.		
	HH	JP 52-128329		10-27-1977	Teikoku Hormone Mfg.		
	II	JP 54-63047		12-16-1980	Glen, et al		
	JJ	GB 1360001		03-16-1970	Neri, et al		
	KK	WO 95 19770		07-25-1995	Sepracor Inc.		
	LL	WO 02 016310		02-28-2002	Dalton, et al		
	MM	WO 98 55153		12-10-1998	Dalton, et al		
	NN	WO 03049675		06-19-2003	GTX Inc.		
	OO	WO 03065992		08-14-2003	GTX Inc.		

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Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Complete if Known	
		Application Number	10/849,039
		Filing Date	May 20, 2004
		First Named Inventor	DALTON, James T.
		Art Unit	1621
(use as many sheets as necessary)		Examiner Name	KUMAR, Shailendra
Sheet	3	of	4
		Attorney Docket Number	P-5235-US14

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	PP	Howard Tucker and Glynne J. Chesterson, J. Med Chem. 1988, 31, pp. 885-887, "Resolution of the Nonsteroidal Antiandrogen - 4'-Cyano-3-[(4-fluorophenyl)sulfonyl]-2-hydroxy-2-methyl-3'-(trifluoromethyl)-propionanilide and the Determination of the Absolute Configuration of the Active Enantiomer "	<input type="checkbox"/>
	QQ	D. McKillop, et al., "Enantioselective metabolism and pharmacokinetics of Casodex in the male rat", Xenobiotica, 1995, Vol. 25, No. 6, 623-634.	<input type="checkbox"/>
	RR	Leonid Kirkovsky, et al., "[¹²⁵ I]-Radionated Bicalutamide Analogs as Potential Imaging Agents for Prostate Cancer", Poster Presentation MEDI 155, 214th ACS National Meeting, Las Vegas, NV, Sept. 7-11, 1997, Department of Pharmaceutical Sciences, University of Tennessee, Memphis, TN 38163	<input type="checkbox"/>
	SS	David T. Baird and Anna F. Glasier, "Hormonal Contraception - Drug Therapy", The New England Journal of Medicine, May 27, 1993, pp. 1543 - 1549	<input type="checkbox"/>
	TT	F.C. W. Wu, "Male Contraception: Current Status and Future Prospects", Clinical Endocrinology, (1988), 29, pp. 443-465	<input type="checkbox"/>
	UU	Carl Djerassi and S.P. Leibo, "A new look at male contraception", Nature, Vol. 370, pp. 11-12	<input type="checkbox"/>
	VV	World Health Organisation Task Force on Methods for the Regulation of Male Fertility, "Contraceptive efficacy of testosterone-induced azoospermia in normal men", The Lancet, Vol. 336, October 20, 1990, pp. 955-959 and 1517-1518	<input type="checkbox"/>
	WW	C. G. Francisco, et al., "Long-acting contraceptive agents: testosterone esters of unsaturated acids", Steroids, January 1990, vol. 55, Butterworths	<input type="checkbox"/>
	XX	John M. Hoberman and Charles E. Yesalis, "The History of Synthetic Testosterone", Scientific American, February 1995, pp. 76-81.	<input type="checkbox"/>
	YY	Leonid Kirkovsky, et al., "Approaches to Irreversible non-steroidal chiral antiandrogens", Department of Pharmaceutical Sciences, University of Tennessee, 47th Southeast/51st Southwest Joint Regional Meeting of the American Chemical Society, Memphis, TN, Nov. 29-Dec. 1, 1995	<input type="checkbox"/>
	ZZ	David J. Handelsman, "Bridging the gender gap in contraception: another hurdle cleared" The Medical Journal of Australia, Vol. 154, February 18, 1996, pp. 230-233.	<input type="checkbox"/>

Examiner Signature		Date Considered	
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/849,039
		Filing Date	May 20, 2004
		First Named Inventor	DALTON, James T.
		Art Unit	1621
(use as many sheets as necessary)		Examiner Name	KUMAR, Shailendra
Sheet	4 of 4	Attorney Docket Number	P-5235-US14

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (where appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	a	Edwards JP, Higuchi RI, Winn DT, Pooley CLF, Caferro TR, Hamann LG, Zhi L, Marschke KB, Goldman ME, and Jones TK. Nonsteroidal androgen receptor agonists based on 4-(trifluoromethyl)-2H-pyrano[3,2-g]quinolin-2-one. Bioorg. Med. Chem. Lett., 9: 1003, 1999.	<input type="checkbox"/>
	b	Zhi L, Tegley CM, Marschke KB, and Jones TK. Switching androgen receptor antagonists to agonists by modifying C-ring substituents on piperidino[3,2-g]quinolone. Bioorg. Med. Chem. Lett., 9: 1009, 1999.	<input type="checkbox"/>
	c	Higuchi RI, Edwards JP, Caferro TR, Ringgenberg JD, Kong JW, Hamann LG, Arienti KL, Marschke KB, Davis RL, Farmer LJ, and Jones TK. 4-Alkyl- and 3,4-diaklyl-1,2,3,4-tetrahydro-8-pyridono[5,6-g]quinolines: potent, nonsteroidal androgen receptor agonists. Bioorg. Med. Chem. Lett., 9:1335,1999.	<input type="checkbox"/>
	d	Hamann LG, Mani NS, Davis RL, Wang XN, Marschke KB, and Jones TK. Discovery of a potent, orally active nonsteroidal androgen receptor agonist: 4-ethyl-1,2,3,4-tetrahydro-6-(trifluoromethyl)-8-pyridono[5,6-g]-quinoline (LG121071). J. Med. Chem., 42: 210, 1999.	<input type="checkbox"/>
	e	Rosen J, Day A, Jones TK, Jones ET, Nadzan AM, and Stein RB. Intracellular receptors and signal transducers and activators of transcription superfamilies: novel targets for small-molecule drug discovery. J. Med. Chem., 38: 4855, 1995.	<input type="checkbox"/>
	f	Dalton JT, Mukherjee A, Zhu Z, Kirkovsky L, and Miller DD. Discovery of Nonsteroidal Androgens. Biochem. Biophys. Res. Commun., 244(1):1-4, 1998.	<input type="checkbox"/>
	g	Edwards JP, West SJ, Pooley CLF, Marschke KB, Farmer LJ, and Jones TK. New nonsteroidal androgen receptor modulators based on 4-(trifluoromethyl)-2-(1H)-Pyrololidino[3,2-g]quinolone. Bioorg. Med. Chem. Lett., 8: 745, 1998.	<input type="checkbox"/>
	h	Eliason, et al "High Throughput Fluorescence Polarization-Based Screening Assays for the Identification of Novel Nuclear Receptor Ligands." Abstracts of Papers, 223 rd ACS National Meeting, Orlando Fla. U.S. 2002	<input type="checkbox"/>
	i	Berger, et al "Concepts and Limitations in the Application of Radiolabeled antiandrogens, estrogens, or androgens as isotropic scanning agents fro the prostate." Invest. Urol. 1975 1391, 10-16	<input type="checkbox"/>
	j	Narayanan, et al "Steroidal Androgens and Nonsteroidal, Tissue Selective Androgen Receptor Modulators (SARM) Regulate Androgen Receptor Function Through Distinct Genomic and Non-Genomic Signaling Pathways." The Endocrine Society – Programs and Abstracts – 89 th Annual Meeting – Paper P1-595.	<input type="checkbox"/>
	k	Yepuru, et al "AN Angrogen Receptor-b Specific Selective Estrogen Receptor Modulator (SERM) Inhibits the Growth of the Prostate Cancer Cells and Stromal-Epithelial Tumor Xenograft." The Endocrine Society – Programs and Abstracts – 89 th Annual Meeting – Paper OR6-3.	<input type="checkbox"/>
	l	Dalton, et al "Therapeutic Promise of Selective Androgen Receptor Modulators (SARs): Preclinical and Clinical Proof-of-Concept Studies." The Endocrine Society – Programs and Abstracts – 89 th Annual Meeting – Paper S41-2.	<input type="checkbox"/>

Examiner Signature	Date Considered
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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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